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PTO/SB/05 (12/97)

UTILITY PATENT APPLICATION TRANSMITTAL <i>(Only for new nonprovisional applications under 37 CFR 1.53(b))</i>	Attorney Docket No.	GE1610	Total Pages	
	First Named Inventor or Application Identifier			
	EPSTEIN et. al.			
	Express Mail Label No.	EL285084928US		

APPLICATION ELEMENTS <i>See MPEP chapter 600 concerning utility patent application contents</i>	TO: Assistant Commissioner for Patents Box Patent Application Washington, DC 20231
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1. ☒ Fee Transmittal Form (e.g., PTO/SB/17) *(Submit an original, and a duplicate for fee processing)*
2. ☒ Specification [Total Pages []]
3. ☒ Drawing(s) (35 USC 113) [Total Sheets []]
4. ☒ Oath or Declaration [Total Sheets [3]]
 - a. ☒ Newly executed (original or copy)
 - b. ☐ Copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional with Box 17 completed) [Note Box 5 below]
 - i. ☐ DELETION OF INVENTOR(S) Signed statement attached deleting Inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
5. ☐ Incorporation By Reference (usable if Box 4b is checked) The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.
6. ☐ Microfiche Computer Program (Appendix)
7. ☐ Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
 - a. ☐ Computer Readable Copy b. ☐ Paper Copy (identical to computer copy)
 - c. ☐ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

8. ☐ Assignment Papers (cover sheet & document(s))
9. ☐ 37 CFR 3.73 (b) Statement *(when there is an assignee)* [] Power of Attorney
10. ☐ English Translation Document *(if applicable)*
11. ☐ Information Disclosure Statement (IDS)/PTO-1449 [] Copies of IDS Citations
12. ☐ Preliminary Amendment
13. ☒ Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
14. ☒ Small Entity Statement(s) [X] Statement filed in prior application. Status still proper and desired
15. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
16. ☐ Other: a) Make the references on the parent application(s) of record herein *(see MPEP 2001.06(b))*.
b)

17. If a **CONTINUING APPLICATION**, check appropriate box and supply the requisite information:

☐ Continuation [] Divisional [] Continuation-in-part (CIP) of prior application No: _____

18. CORRESPONDENCE ADDRESS

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October 19, 1904

Telex: 429283 PATSLAW

Express Mail Label No. EL285084928US

Re: Gordon H. EPSTEIN
New U. S. Patent Application
Priority of U.S. Provisional Application No. 60/102,636
Serial No.: Unknown Filed: Herewith
Attorney Docket No. GE1610
"COMPONENT MIXING CATHETER"


No Fees are due or authorized to be paid at this time.

We enclose herewith:

- ☒ New Patent Application Transmittal Letter
☒ New Patent Application including specification (~~18~~ pages), claims (~~3~~ pages),
 and abstract (1 page)
☒ (~~12~~ 1) Sheets of drawings
☒ Declaration (unexecuted)
☒ Statement of Small Entity (copy filed with provisional)
☒ Acknowledgement Postcard

Applicant hereby petitions under 37 CFR 1.136 or other applicable rule to have the response period extended the number of months necessary to render the attached communication timely if a petition is required.

Respectfully submitted,


Anthony H. Handal
Reg. No. 26,275

Applicant or Patentee: EPSTEIN, Gordon H.

Serial No.: Unknown

Attorney's Docket No.: GE1300

Filed: Herewith

For: _____

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 CFR 1.9(f) and 1.27(b))-SMALL BUSINESS CONCERN

I hereby declare that I am

- ☐ the owner of the small business concern identified below:
☒ an official for the small business concern empowered to act on behalf of the concern identified below.

NAME OF CONCERN BioSurgical Corporation

ADDRESS OF CONCERN 5990 Stoneridge Drive, Pleasanton CA 94588

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18 and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled MULTIPURPOSE APPLICATOR AND METHOD, WITH SURGICAL USES by the inventor Gordon H. EPSTEIN described in

- ☒ the specification filed herewith
☐ Patent Application Serial No. _____, filed _____
☐ patent No. _____, issued _____

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(d) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e). *NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

FULL NAME _____ ADDRESS _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(h))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING Gordon Howard EPSTEIN

TITLE OF PERSON OTHER THAN OWNER Chief Technology Officer

ADDRESS OF PERSON SIGNING 135 Kootenai Drive, Fremont CA 94539

SIGNATURE Gordon Howard Epstein

DATE 7/17/98

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IMPROVED COMPONENT MIXING CATHETER

CROSS-REFERENCE TO RELATED APPLICATIONS

(Continuation status not claimed.)

- 1 This application discloses subject matter in the general field of commonly
2 assigned copending United States patent applications nos. 08/838,078 and
3 08/839,614, both filed April 15, 1997, to patent application no. 08/946,364
4 filed October 7, 1997, to patent application no. 09/037,160 filed March 9,
5 1998 all naming Gordon H. Epstein as first inventor, and to U.S. patent
6 application no. (unknown) filed May 21, 1998 naming Mitchell E. Levinson
7 as first inventor and entitled "SEALANT APPLICATOR AND METHOD
8 EMPLOYING IMPULSE CLEARING". The disclosures of the
9 aforementioned United States patent applications, "the above applications"
10 are hereby incorporated herein by reference thereto as is the disclosure of
11 provisional application number 60/102,636 from which the present
12 application claims priority. *Continuation status is not being claimed at this time.*
13 This statement is made without prejudice to applicant's right to claim continuation
14 status at any time during copendency of the present application with respect to
15 another application.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT
(Not applicable.)

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to an apparatus and method for applying component parts of a sealant which when mixed transforms from a fluidic state to a non-fluidic state. In particular but not exclusively, the present invention is directed to an apparatus and process in which sealant components are mixed prior to being applied to biological tissue to effect hemostasis or achieve other therapeutic results.

2. Description of Related Art Including Information Disclosed under 37 CFR 1.97 and 37 CFR 1.98

Use of tissue sealants and other biological materials is an important emerging surgical technique, well adapted for the operating room or field environments such as the doctor's office or mobile medical units. In addition, the application of such sealants via a catheter provides a non evasive medical technique. Preferred sealants include fibrin sealants which are formed from blood plasma components and comprise, on the one hand, a first component containing fibrinogen and Factor XIII and on the other hand a second component which usually includes thrombin, and calcium ions.

The fibrinogen is capable of a polymerizing and being cross-linked to form a solid fibrin clot when the components are mixed. The necessary additional factors to simulate relevant portions of the natural blood coagulation cascade are suitably distributed between the fibrinogen and thrombin

1 components.

2

3 High levels of protection against transmission of infections or induction of
4 immunological reactions can be assured by using an autologous or single-
5 donor source for both components. Such sealants are highly effective, are
6 biologically degraded without residue and may promote wound healing.

7

8 Depending upon the potency of the particular formulations employed,
9 coagulation of the sealant may take place very rapidly, yielding a gel within
10 perhaps 10 or 20 seconds after mixing of the two components. Though often
11 very desirable for surgical reasons, such fast-acting properties present
12 potential problems of fouling or clogging. These problems must be
13 overcome in devising suitable applicators, and methods of application.

14

15 A popular manually operable applicator for such two-component sealants
16 employs a dual syringe construction wherein two syringes, connected by a
17 yoke, each provide a reservoir for one of the components. In most prior
18 devices, the sealant components are discharged in separate streams and
19 mixed externally of the applicator. Such applicators are similar in principle
20 to household epoxy glue applicators commonly available in hardware
21 stores. Achieving effective mixing externally of the applicator is
22 problematic.

23

24 In United States patent No. 5, 266,877, and the above applications, the
25 present inventor teaches various constructions of a dual syringe applicator
26 wherein the fluid sealant components are mixed internally.

27

28 Antanavich et al. United States Patent number 5,585,007, whose disclosure

1 and references are hereby incorporated herein by reference thereto, provides
2 an extensive discussion of the literature relating to fibrinogen sealant
3 preparation (column 1, line 20 to column 4, line 62) and applicators column
4 4 line 62 to column 5, line 14), as well as a bibliography, (columns 6-10) and
5 is a helpful guide to the teachings of prior workers in the field.

6

7 In one or more of the above copending applications the possibility of
8 retrograde clearing of the mixed fluids pathway within the applicator, using
9 suction, is also disclosed. The applicator is provided with suitable suction
10 conduits and valving to apply suction to the work surface, to prepare it for
11 the application of sealant, for example by removing fluids. As taught, the
12 valving is operable to effect retrograde clearing of a sealant dispensing
13 pathway. Enhanced mixing is possible for example, by impingement and
14 problems of fouling by deposited solids are avoided.

15

16 Such applicators, and methods, are remarkably effective for applying
17 sealants to exposed biological surfaces. However, it would be desirable to
18 provide a surgeon, or other user, with additional choices, for example, an
19 applicator and method that could effectively apply sealant to internal
20 biological locations.

21

22 One difficulty is that the coagulating nature of the sealants causes the
23 discharge opening or openings of an application device to become clogged
24 so that flow out of the applicator slows down or stops.

25

26 While the above-referenced copending applications disclose effective
27 clearing-enabled sealant application devices and methods, their techniques
28 are generally intended for application of sealant to exposed and accessible

1 work surfaces.

2

3 There is accordingly a need for a sealant applicator and method that can be
4 used to reach an unexposed or inaccessible location.

5

6

SUMMARY OF THE INVENTION

7 The present invention solves this problem by providing a sealant applicator
8 comprising a dual catheter communicating with fluid sealant agent sources,
9 for example, two internal reservoirs, which sealant applicator can effectively
10 deliver multiple sealant components to a remote tip of the catheter for
11 mixing and dispensing to an area of application. Preferably this catheter is a
12 dual catheter having one catheter movably mounted with respect to another,
13 for example longitudinally within the other. The movable catheter is then
14 used as a plunger to unclog the openings.

15

16 The present invention enables an effective sealant composition to reach an
17 area of application by mixing the sealant components to application or
18 contact with the work surface and providing for removal of coagulated
19 sealant.

20

21 Preferably, although not necessarily, the sealant is a biological sealant, for
22 example a tissue adhesive, and the area of application is a biological tissue
23 subject to surgery. The sealant components can comprise a first, structural
24 component capable of gelling, and preferably of solidification and a second,
25 activation component which activates such gelling and, optionally,
26 solidification. More preferably, the sealant is a tissue sealant and the first
27 component comprises fibrinogen and the second component comprises, or
28 can generate a fibrinogen activator, especially thrombin or an equivalent

1 thereof.

2

3 The invention also provides a novel surgical method of applying sealant to
4 unexposed or internal biological surfaces, e.g. human or animal anatomical
5 surfaces, that are accessible to a catheter. The use of a dual catheter, which
6 receives a flow of multiple sealant components and mixes the sealant
7 components at the distal end of the catheter, allows the distal end of the
8 catheter to apply a mixed sealant a work site.

9

10

BRIEF DESCRIPTION OF THE DRAWINGS

11 One way of carrying out the invention is described in detail below with
12 reference to the drawings which illustrate one or more specific embodiments
13 of the invention and in which:

14 **Figure 1** is a cross sectional elevational view of a catheter sealant
15 applicator according to the present invention;

16 **Figure 2** is a complete bottom view along lines 2-2 of Figure 1;

17 **Figure 3a** is a view similar to Figure 1 illustrating operation of the
18 applicator of the present invention;

19 **Figure 3b** is a cross sectional view along the lines 3b-3b of Figure 3a;

20 **Figure 3c** is a cross sectional view of an alternative embodiment of the
21 present invention;

22 **Figure 4** is a cross sectional elevational of an alternative embodiment of
23 the present invention;

24 **Figure 5** is a cross sectional view illustrating operation of the present
25 invention;

26 **Figure 6** is a cross sectional view illustrating operation of the present
27 invention;

28 **Figure 7** is a cross sectional view illustrating operation of the present

1 invention;
2 **Figure 8** is a cross sectional view illustrating operation of the present
3 invention;
4 **Figure 9** is a perspective view of a component part of the present
5 invention;
6 **Figures 10 and 10a** are a cross sectional view illustrating an alternative
7 embodiment of the present invention;
8 **Figures 11 and 11a** are a cross sectional view illustrating an alternative
9 embodiment of the present invention;
10 **Figure 12** is a cross sectional view illustrating an alternative embodiment
11 of the present invention;
12 **Figure 13** is a cross sectional view illustrating an alternative embodiment
13 of the present invention;
14 **Figure 14** is a cross sectional view illustrating an alternative embodiment
15 of the present invention;
16 **Figure 15** is a cross sectional view illustrating an alternative embodiment
17 of the present invention;
18 **Figure 16** is a perspective view of a further embodiment of the invention
19 employing a plug-like inner catheter, in a retracted position
20 within an outer catheter shown as being transparent to reveal
21 the inner structure; and
22 **Figure 17** is a view similar to Figure 16 with the plug-like inner catheter in
23 an advanced position.
24

25 DESCRIPTION OF THE PREFERRED EMBODIMENTS

26 Referring now to Figures 1 and 2, a sealant applicator 10 is illustrated.
27 Applicator 10 comprises a pair of inner and outer coaxial catheters 12 and
28 14. In the preferred embodiment inner and outer catheters 12 and 14 are

1 elongated tubes. Inner and outer catheters 12 and 14 are constructed out of
2 any suitable, preferably sterilizable material, for example, stainless steel or
3 polypropylene, and may be rigid or flexible, or may comprise both rigid and
4 flexible components along their lengths. Typically, catheters are
5 substantially longer than the dispensing cannulas described in preferred
6 embodiments of the parent application, having, for example, a length of at
7 least 10 cm, often at least 20 cm and sometimes being substantially longer,
8 for example a meter or more. Commonly, catheters are flexible, or have a
9 flexible portion.

10

11 Inner catheter 14 defines an area 16 and is of a smaller diameter than outer
12 catheter 12, this allows outer catheter 12 to surround inner catheter 14
13 leaving a second area 18.

14

15 Outer catheter 12 is configured to have an opening 20 for dispersing a mixed
16 sealant 22.

17

18 Sealant 22 is typically comprised of a first sealant agent or component 24
19 and a second agent or component 26. Component 24 is contained within
20 area 16 and component 26 is contained with area 18. Inner catheter 14 has
21 an opening 28 for discharge of component 24, and in the position shown in
22 Figure 1 is retracted behind opening 20 of outer catheter 12 to provide a
23 mixing volume 29.

24

25 In the preferred embodiment areas 16 and 18 and their respective ratios are
26 of such a configuration as to provide desired proportions of components 24
27 and 26 to provide a sealant 22 in accordance with the required parameters.
28 As may be desired, areas 16 and 18 and their corresponding volumes may be

1 varied to provide a sealant 22 of various characteristics. For instance, a
2 sealant that may require a longer time to cure or a sealant that may require
3 lesser time to cure by using a lesser or greater proportion or concentration of
4 activator, e.g. thrombin for a fibrinogen sealant.

5

6 Areas 16 and 18 are of sufficient size to allow for unimpeded flow of the
7 sealant components.

8

9 Inner catheter 14 is slidably or otherwise movably mounted with respect to
10 outer catheter 12 to permit relative movement of inner catheter 14 in the
11 directions of arrow 30.

12

13 The movement of outer catheter 12 allows opening 28 of inner catheter 14 to
14 be positioned within outer catheter 12 and away from opening 20. This
15 position allows components 24 and 26 to mix in an area in close proximity to
16 opening 20. Moreover, and as illustrated in Figure 3a, the position of
17 opening 28 may be further retracted with respect to outer catheter 12. This
18 positioning will provide a larger mixing volume 29 allowing for a longer
19 mixing time of component 24 and 26.

20

21 Alternatively, opening 28 may be positioned closer to opening 20, if desired,
22 to reduce the volume of mixing volume 29 and the time components 24 and
23 26 are in contact with each other inside applicator 10. This may be
24 appropriate for a very fast setting sealant.

25

26 To stabilize inner catheter 14 and maintain the appropriate mixing volumes
27 of components 24 and 26, a stabilizing ring 27 (as illustrated by the dashed
28 lines in Figure 3a) or the equivalent thereof can be affixed to inner catheter

1 14 and extend outwardly to outer catheter 12. Stabilizing ring 27 provides
2 stability to inner catheter 14 and is configured to allow component 26 to
3 flow through the same.
4

5 Alternatively, and depending on the length of catheters 12 and 14, a
6 plurality of stabilizing rings 27 may positioned within applicator 10 to
7 provide stability to inner catheter 14.
8

9 The movement of inner catheter 14 may be effected by any suitable
10 mechanism for example, a proximally located ratchet and pawl mechanism
11 as illustrated in Figure 4. In this embodiment a locking mechanism 32
12 restricts the movement of the proximal end of inner catheter 14 by engaging
13 with a plurality of nubs 34. Movement of mechanism 32 into a position, as
14 illustrated by the dashed lines in Figure 4 will once more allow inner
15 catheter 14 to move in the direction of arrow 30. Mechanism 32 may be
16 configured to have a conveniently placed trigger to facilitate the release.
17

18 In addition, and as an alternative, mechanism 32 can work in conjunction
19 with a return spring 35 which is depressed as inner catheter 14 is depressed.
20 Accordingly, as mechanism 32 is released the force of spring 35 acts to
21 return inner catheter 14 to its original position.
22

23 Optionally, inner catheter 14 may be provided with graduated markings 36.
24 Markings 36 can indicate the relative position of opening 28 of inner catheter
25 14 with respect to opening 20 of outer catheter 12. For instance, a marking
26 of zero would indicate that opening 28 and opening 20 are flush with each
27 other. Other markings such as +1, +2, +3, or -1, -2, -3 would indicate the
28 respective location of opening 28 with respect to 20.

1 In yet another embodiment markings 36 can indicate the flow output of
2 sealant 22 depending on the position of opening 28. Depending on the size
3 of catheters 12 and 14, markings 36 can be configured to indicate flow
4 output of mixed sealant 22, such as millimeters per second or any other
5 suitable indicator of flow output. In addition, markings 36 may also be
6 configured to refer to the mixture ratio of component 24 with respect to
7 component 26.

8
9 The movement of inner catheter 14 with respect to outer catheter 12 also
10 allows a user to conveniently purge any clot of hardened sealant 22 from
11 opening 20, as will now be further explained.

12
13 Turning now to Figures 5 and 6, and as previously discussed the internal
14 mixing of components 24 and 26 effects coagulation of sealant 22. However,
15 such coagulation may cause a clot 38 to block opening 20. This problem is
16 addressed by the mobility of inner catheter 14. To facilitate the removal of
17 clot 38 the user can simply move inner catheter 14 to the position illustrated
18 in Figure 6. Such movement may be accomplished through the use of a
19 trigger mechanism as described with reference to Figure 4, or any other
20 suitable mechanism.

21
22 In yet another embodiment stabilizing ring 27 (Figures 3a and 3b) is also
23 used as a plunger for removal of clot 38. In this embodiment stabilizing ring
24 27 is slidably mounted in area 18 positioned between inner catheter 14 and
25 outer catheter 12. Movement of ring 27 is effected through the use of a user
26 manipulated trigger mechanism. To remove clot 38 the user simply causes
27 ring 27 to move towards opening 20. Such movement will dislodge clot 38.
28 As an alternative, a plurality of stabilizing rings 27 may be positioned

1 throughout area 18.

2

3 Stabilizing ring 27 allows component 26 to flow through area 18
4 unimpeded, however, stabilizing ring 27 is constructed in such a manner as
5 to force clot 38 from opening 20 once stabilizing ring 27 has made contact
6 with clot 38.

7

8 One such configuration is that of a spoked wheel (Figure 3b) wherein the
9 spokes 33 of stabilizing ring or rings 27 define a plurality of openings 35.
10 Openings 35 are large enough to allow component 26 to pass through while
11 being small enough to force the removal of clot 38.

12

13 Alternatively, ring or rings 27 is a disk having a plurality of smaller
14 openings 35 (Figure 3c).

15

16 Movement of stabilizing ring 27 is effected through the use of a trigger
17 mechanism, such as a plunger or the equivalent thereof, positioned at the
18 proximal end of applicator 10 which is conveniently accessed by the user's
19 finger or thumb.

20

21 In yet another embodiment, ring or rings 27 are secured to inner catheter 14.
22 Thus, as the user manipulates or moves inner catheter 14 ring 27 also moves.

23

24 In a still further embodiment, rings 27, or inner catheter 14 with rings 27
25 secured to it, are capable of being rotated as they are being depressed. Such
26 rotation will enhance the dislodging of clot 38.

27

28 Other clot removal techniques such as those illustrated in Figures 7 and 8

1 may be utilized. In this sequence, a user first moves inner catheter 14 into
2 the position illustrated in Figure 7. The movement will dislodge clot 38
3 from opening 28 of inner catheter 14. Then the user moves inner catheter 14
4 into the position illustrated in Figure 8. This movement allows inner
5 catheter 14 to act as a plunger which will dislodge clot 38 from opening 20
6 thereby discharging clot 38 from applicator 10.

7
8 Alternatively, and as illustrated by the dashed lines in Figure 8, catheters 12
9 and 14 may be constructed out of a flexible material capable of being
10 manipulated into the squeezed position illustrated by the dashed lines. This
11 configuration allows the distal end of applicator 10 to be compressed to
12 dislodge clot 38. In addition, small amounts of components 24 and 26 will
13 be forcibly dispelled during this compression and will aid in the clearing of
14 applicator 10. The manipulation of applicator 10 can be performed by the
15 fingers of the user or a pinching mechanism which could be hand held or
16 adhered to applicator 10.

17
18 Alternatively, catheters 12 and 14 may be constructed out of a flexible
19 material capable of be manipulated at the proximal end of applicator 10 to
20 effectively pinch off the supply of components 26 and 24. The compression
21 of catheters 12 and 14 at the proximal end also causes small amounts of
22 components 24 and 26 to be discharged. Such placement of a pinching
23 mechanism or pinching capability at the proximal end of applicator 10 also
24 provides for an ergonomic device.

25
26 Openings 28 and 20 may be equipped with a closing mechanism, such as a
27 removable cover 31 (illustrated in Figure 9) which prevents unrestricted flow
28 of components 24 and 26 from inner and outer catheters 12 and 14 between

1 uses.

2

3 Referring now to Figures 10 and 10a an alternative embodiment of the
4 present invention is illustrated. In this embodiment, components and/or
5 parts performing analogous or similar functions are numbered in multiples
6 of 100. Here an opening or plurality of openings 128 are positioned along
7 the elongated portions or walls of catheter 114. These openings allow
8 component 124 to mix with component 126 throughout an extended mixing
9 volume 129 prior to discharge of mixed sealant 122 from opening 120. This
10 embodiment allows for a particularly effective mixing of components 124
11 and 126 prior to application.

12

13 In this embodiment the end of catheter 114 is closed. Accordingly, mixed
14 sealant 122 is applied to the required location through opening 120.
15 Catheter 114 may also be positioned to apply sealant 122 as illustrated in
16 Figures 11 and 11a.

17

18 In the case where a clot 138 has blocked opening 120, catheter 114 may also
19 be used as a plunger to remove clot 138 (as illustrated by the dashed lines in
20 Figure 11a).

21

22 In yet another embodiment, and as illustrated in Figure 12, catheter 214 is
23 configured to have a plurality of smaller openings 228 throughout a selected
24 length of the distal end of the catheter 214, for example 1 or 2 cm., or the
25 entire surface of catheter 214. This configuration allows for an even greater
26 mixing volume 229. Preferably, sufficient pressure of sealant agent or
27 component is maintained in inner catheter 214 to ensure avoid possible
28 backflow and clogging of openings 228 owing to mixing of the sealant

1 components in the openings.

2

3 In addition and in order to aid in the clot expulsion as depicted in Figures 6-
4 8 small amounts of components 24 and 26 may also be expelled with the clot
5 to ensure that all of the clot is removed from applicator 10.

6

7 Referring now to Figure 13, one possible supply connection of inner and
8 outer catheters 12 and 14 is illustrated. A flexible connector 14a is connected
9 to the proximal end of inner catheter 14. Flexible connector 14a supplies
10 area 16 with sealant component 24. The flexible nature of connector 14a
11 allows inner catheter 14 to move in the directions of arrow 30.

12

13 Movement of inner catheter 14 is facilitated by the manipulation of an
14 actuating mechanism 40 which is secured to inner catheter 14 via a clamping
15 device 42. Such manipulation causes a corresponding movement of inner
16 catheter 14, and may be effected by a manual control (not shown), for
17 example a spring-loaded depressible button or trigger.

18

19 A flexible gasket 44 allows for movement of inner catheter 14 while
20 providing a secure seal around catheters 14 and 12.

21

22 Outer catheter 12 is also connected to a connector 12a. Connector 12a
23 supplies area 18 with sealant component 26. Connector 12a may also be
24 flexible, however connector 12a may be constructed out of a more rigid
25 material.

26

27 Referring now to Figure 14 yet another alternative embodiment of the
28 supply connection of the present invention is illustrated. Here both inner

1 and outer catheters 314 and 312 are connected to connectors 312a and 314a.
2 In this embodiment catheter 312 is configured to have a flexible and
3 expansible portion 346, which can, for example, be of fanfold or accordion-
4 like bellows construction and is located intermediate to catheter 312 and
5 connector 312a. Flexible portion 346 allows for constriction and expansion
6 of outer catheter 312 in the directions depicted by arrow 330. Movement of
7 catheter 312 is effectuated by an actuating mechanism 340. As mechanism
8 340 advances or retracts catheter 312 also moves in the same direction.

9
10 Referring now to Figure 15 an alternative embodiment of the distal, delivery
11 end of applicator 10 is illustrated. Here catheter 12 is configured to have a
12 tapered end, constricting the flow of sealant components to provide a
13 mixing volume 29 with strong turbulence. The outer diameter of inner
14 catheter 14 can be as large as opening 20, thus when inner catheter 14 is
15 advanced, it exerts a precise plug-removal clearing action on the reduced
16 diameter tip of outer catheter 12.

17
18 The embodiment of the invention shown in Figures 16-17, comprises a modified
19 clearing-enabled, dual catheter sealant applicator 360 which can be fabricated from
20 suitably soft or resilient materials, to have a flexible or malleable end or tip 362 to
21 facilitate or enhance engagement of the applicator with, and entry of the applicator
22 into, living tissues, for example, the ear, the nose or the throat. The material of
23 applicator 360, at least at tip 362, should preferably be sterilizable and non-
24 absorbent, as well as soft, or deformable, and resilient, and may for example, be a
25 silicone rubber.

26
27 Catheter sealant applicator 360 comprises a hollow outer sheath 364, an inner plug
28 366 which has an axial bore 368 and external channels 370, and a supply lumen 372

1 press-fitted into plug 366. As shown, four symmetrically disposed channels 370 are
2 provided, but other numbers of channels 370 such as three, six or eight may be
3 employed. The outer diameter of plug 366 is a close sliding fit within the inner
4 diameter of sheath 364. The cross-sectional areas of channels 370 and bore 368 are
5 selected to provide desired relative flow rates of sealant agents, which relative flow
6 rates may be varied, or selected, by using plugs 366 of different configurations.
7 Such diverse plugs 366 may be supplied each with a lumen 372, or may be
8 interchangeably fittable to one or more lumens 372. Optionally, channels 370 on
9 plug 366 can taper outwardly, in the fluid delivery direction, which is to say
10 distally, to increase the channel area in the direction of flow and facilitate clearing
11 and the removal of clots.

12
13 A further option is for channels 370 to have a helical configuration, as shown,
14 simulating rifling, to impart spin to the fluid travel to enhance mixing of the sealant
15 agents. In such case a still further option is for channels 370 to be twisted in
16 opposed directions around plug 366, to impart countercurrent flows and further
17 enhance mixing.

18
19 Preferably, the sealant catalyst, for example, in the case of a fibrinogen sealant,
20 thrombin or other fibrinogen activator, is supplied through lumen 372 to bore 368
21 in plug 366, and fibrinogen or other polymerizable sealant agent, is supplied in the
22 space between the outside of the lumen and the inside diameter 374 of sheath 364.

23
24 For application of sealant, the forward or distal face of plug 366 is slightly retracted
25 behind the distal end of sheath 364 to allow mixing of the two agents to take place
26 in a mixing volume disposed generally within the sheath 364. As with other
27 embodiments described herein, significant mixing of the sealant components takes
28 place before delivery of the sealant agents to, or contact of the sealant agents with,
29 the target work surface.

1 Once a cycle of sealant application is complete, tip 362 can be cleared of any clot or
2 other material, by advancing lumen 372, driving plug 366 forwardly inside sheath
3 364 and expelling the clot. If necessary, the clot can be freed from the face of plug
4 366, or loosened, by dispensing a small amount of sealant.

5

6 The invention provides a novel surgical method of applying sealant to
7 unexposed or internal biological surfaces, e.g. human or animal anatomical
8 surfaces, that are accessible to a catheter, for example, inner ear structures,
9 the veins and arteries and organs such as the heart that are accessible via
10 veins and arteries, the bladder, and so on. The method comprises use of a
11 dual catheter such as described hereinabove, which is coupled to a sealant
12 applicator to receive a flow of multiple sealant components from the
13 applicator and to mix the sealant components at the distal end of the
14 catheter, and insertion of the catheter into a body organ to advance the
15 distal end of the catheter to a work site, operation of the sealant applicator
16 to dispense sealant from the distal end of the dual catheter, and removal of
17 the dual catheter from the body organ. After removal, the tip of the dual
18 catheter will usually be cleared of any clog by operating the inner catheter as
19 a plunger and ejecting the clog to waste. In an exceptional case, and with
20 due care on the part of the surgeon or other operator, the inner catheter may
21 be advanced while the dual catheter is inserted into a body organ, to free the
22 dual or outer catheter, or clear an obstruction or, possibly, to manipulate
23 the work surface.

24

25 While illustrative embodiments of the invention have been described above,
26 it is, of course, understood that various modifications will be apparent to
27 those of ordinary skill in the art. Many such modifications are contemplated
28 as being within the spirit and scope of the invention.

1 **Claims**

2 1. A multi-component sealant applicator comprising a catheter for delivering
3 sealant and a mixing volume within the catheter for mixing sealant multiple sealant
4 components prior to discharge from a distal end of the catheter.

5
6 2. An applicator according to claim 1 comprising a dual catheter, each
7 catheter communicating with one of a pair of fluid sealant agent sources.

8
9 3. An applicator according to claim 1 wherein one catheter is movably
10 mounted with respect to the other.

11
12 4. An applicator according to claim 1 wherein one catheter is mounted
13 for longitudinal movement within the other.

14
15 5. An applicator according to claim 1 comprising a clearing system to
16 clear undesired material from the mixing volume or the vicinity of the
17 mixing volume.

18
19 6. An applicator according to claim 5 comprising a dual catheter, each
20 catheter communicating with one of a pair of fluid sealant agent sources
21 wherein one catheter is mounted for longitudinal movement within the
22 other and the inner catheter is usable as a plunger to remove clogs.

23
24 7. An applicator according to claim 2 comprising a stabilizer member to
25 locate one catheter with respect to the other.

26
27 8. An applicator according to claim 4 comprising a stabilizer member to
28 locate one catheter with respect to the other wherein the stabilizer member

1 comprises ring disposed in the outer catheter around the inner catheter and
2 provided with openings for the passage of sealant component.

3

4 9. An applicator according to claim 2 comprising a reciprocal drive
5 mechanism proximally coupled with the dual catheter to move one catheter
6 longitudinally back and forth with respect to the other.

7

8 10. An applicator according to claim 9 wherein the drive mechanism
9 comprises a ratchet and pawl.

10

11 11. An applicator according to claim 2 provided with graduated markings
12 to indicate the relative position of one catheter with respect to the other.

13

14 12. An applicator according to claim 8 comprising a clot clearing
15 mechanism operative to move the stabilizer ring into engagement with a clot
16 to be cleared.

17

18 13. An applicator according to claim 12 wherein the clot clearing
19 mechanism comprises a manually actuatable trigger.

20

21 14. An applicator according to claim 2 wherein the dual catheters have
22 distal tips resiliently deformable to expel clots.

23

24 15. An applicator according to claim 2 comprising a cover to close the
25 distal end of the dual catheter.

26

27 16. An applicator according to claim 4 wherein the inner catheter
28 comprises multiple lateral openings in the vicinity of its distal end for flow

1 of a sealant component to provide a mixing volume in the outer tip.

2

3 17. An applicator according to claim 16 wherein the end of the inner
4 catheter is closed.

5

6 18. An applicator according to claim 2 wherein the proximal ends of the
7 catheters are coupled to sources of sealant components, one catheter being
8 coupled through a flexible gasket allowing for relative movement of the
9 catheters and providing a fluid seal.

10

11 19. A method of applying a multi-component sealant to anatomical
12 surfaces, that are accessible to a catheter, comprising flowing multiple
13 sealant components through a longitudinally compartmented catheter and
14 mixing the components in the catheter immediately prior to discharge.

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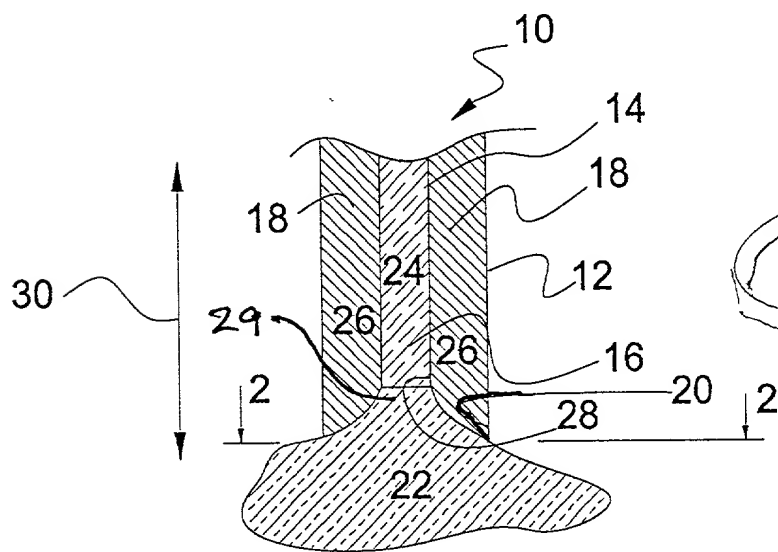


Figure 1

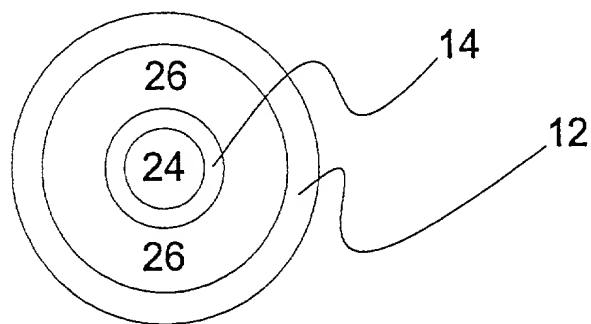


Figure 2

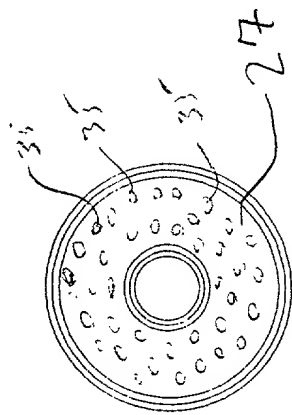


Figure 3c

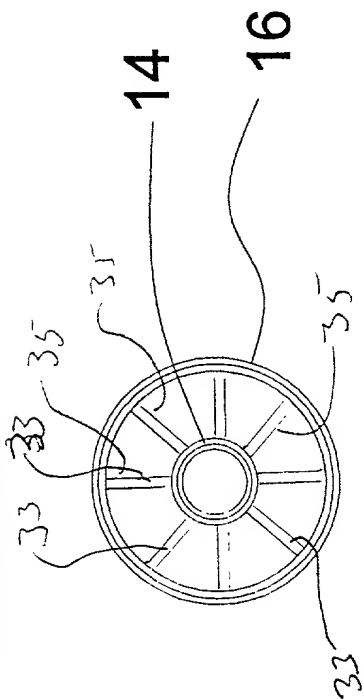


Figure 3b

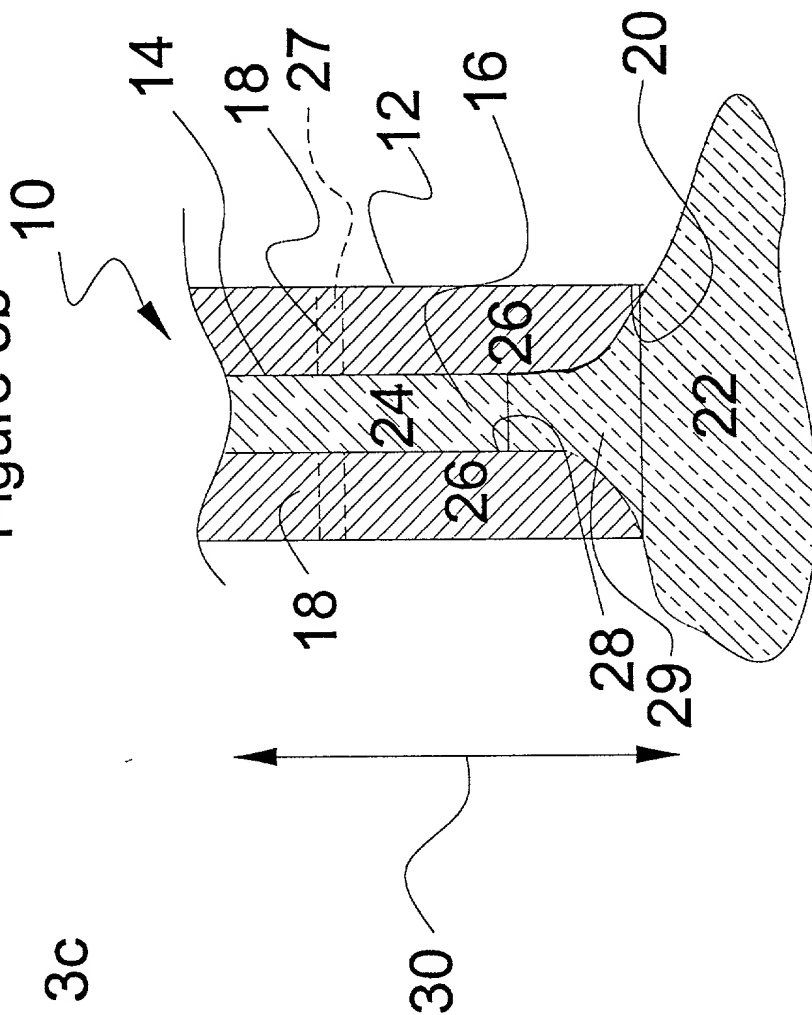


Figure 3a

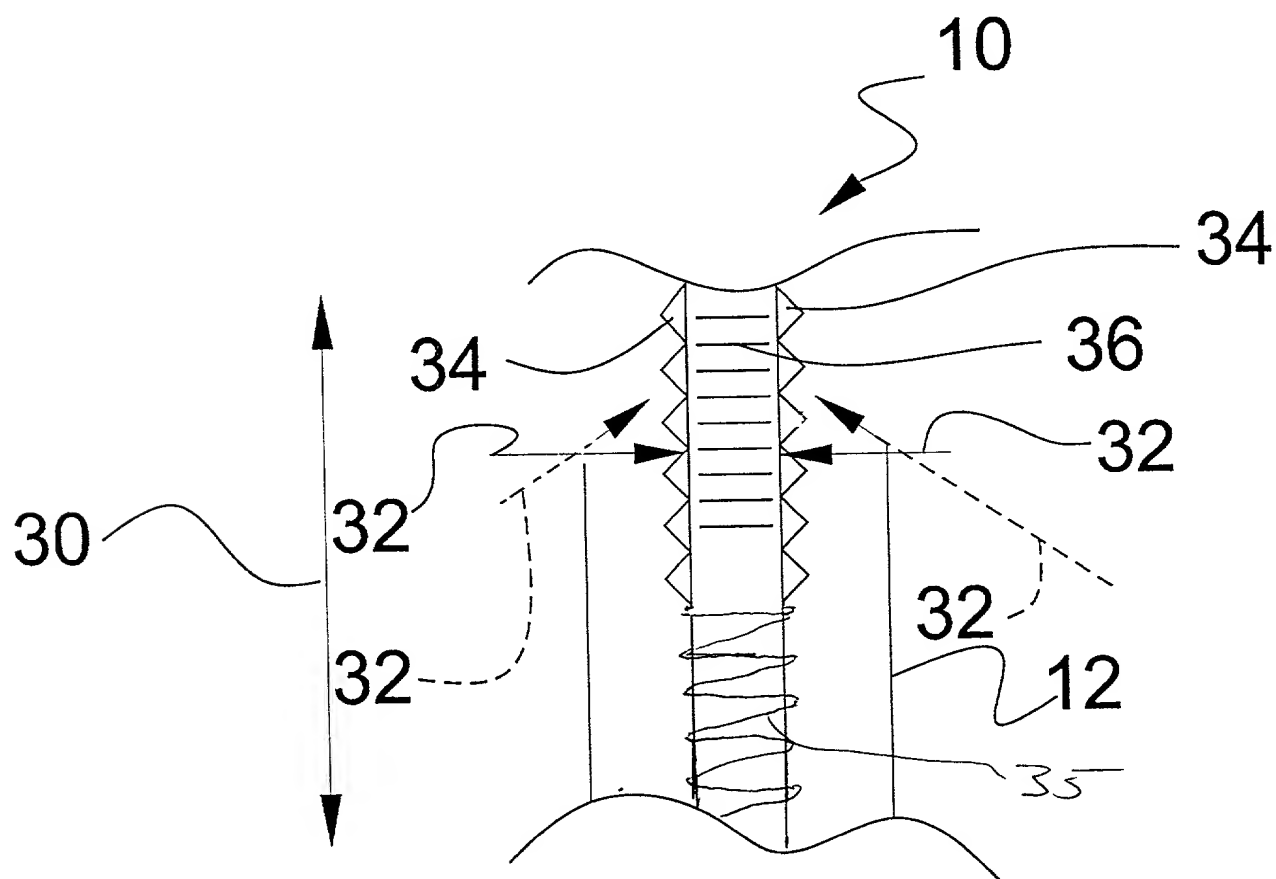
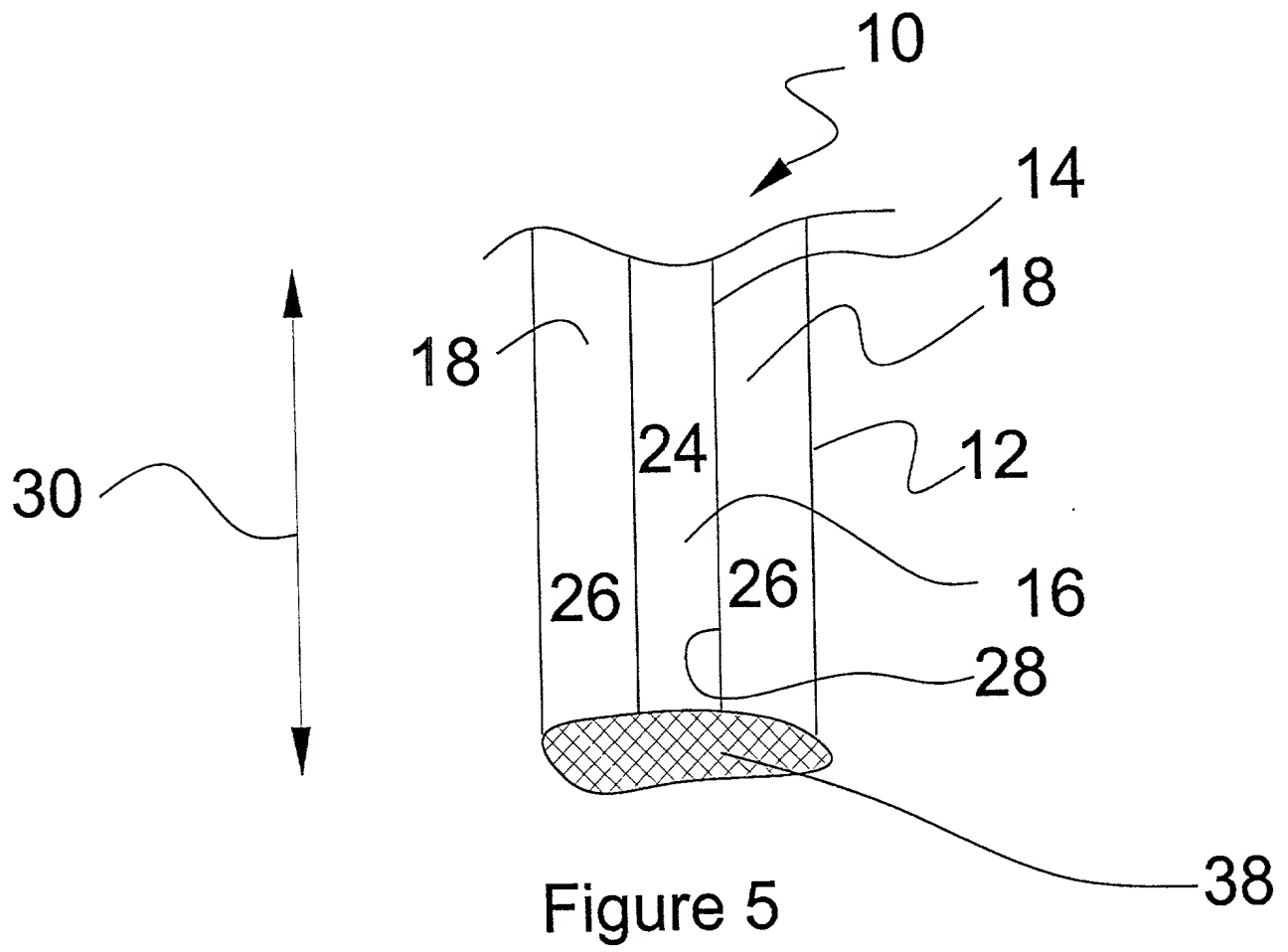


Figure 4

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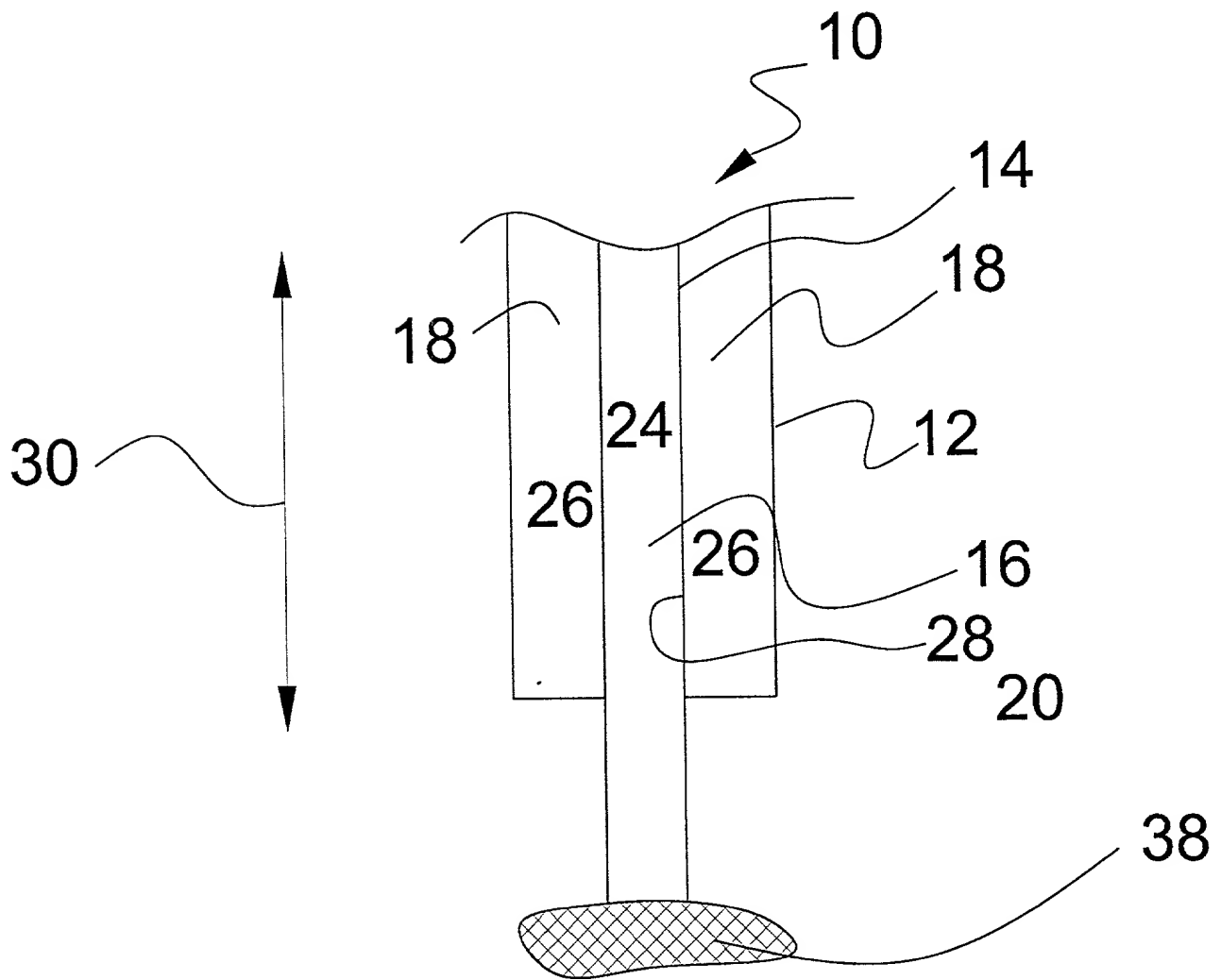
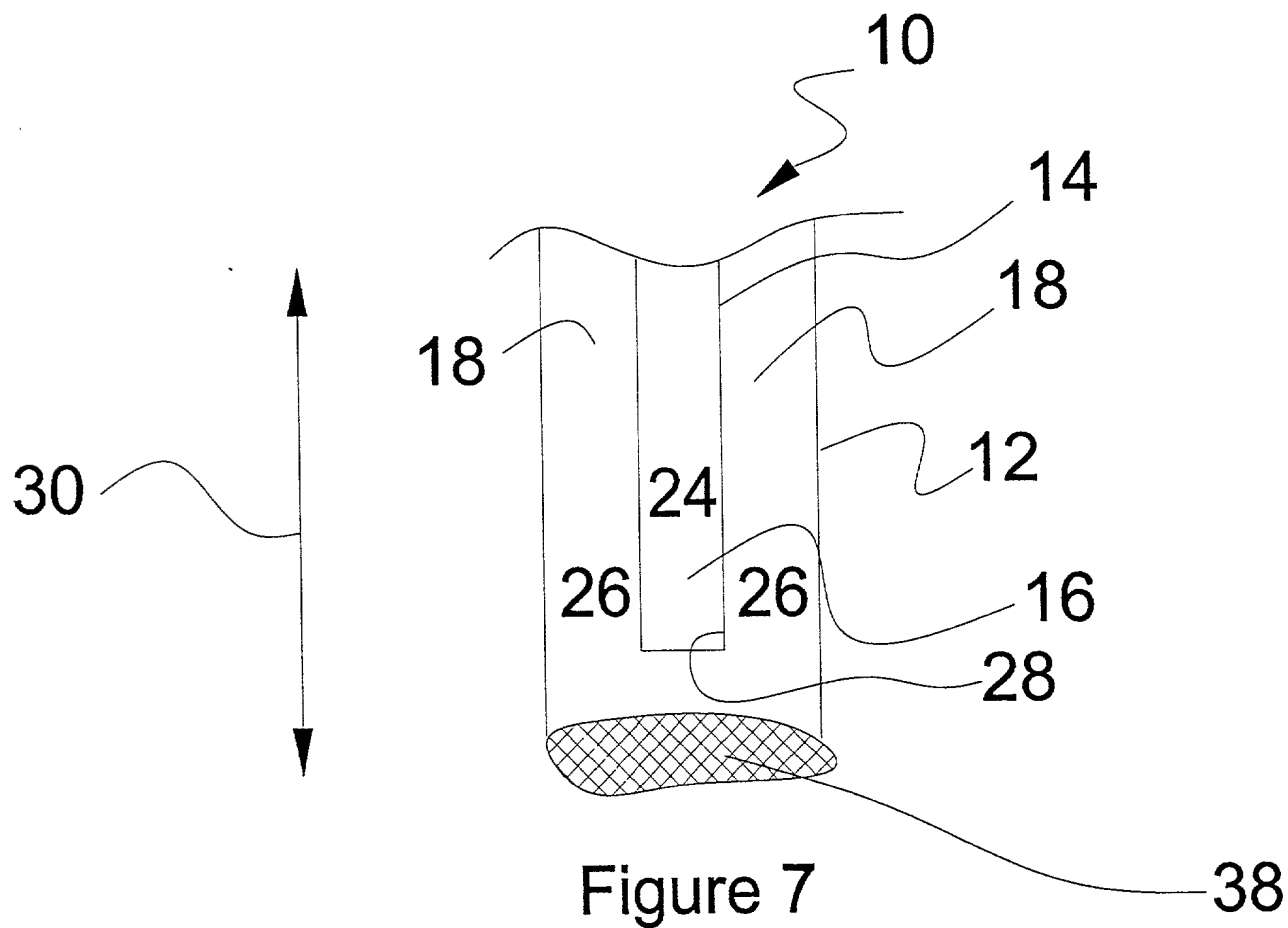


Figure 6



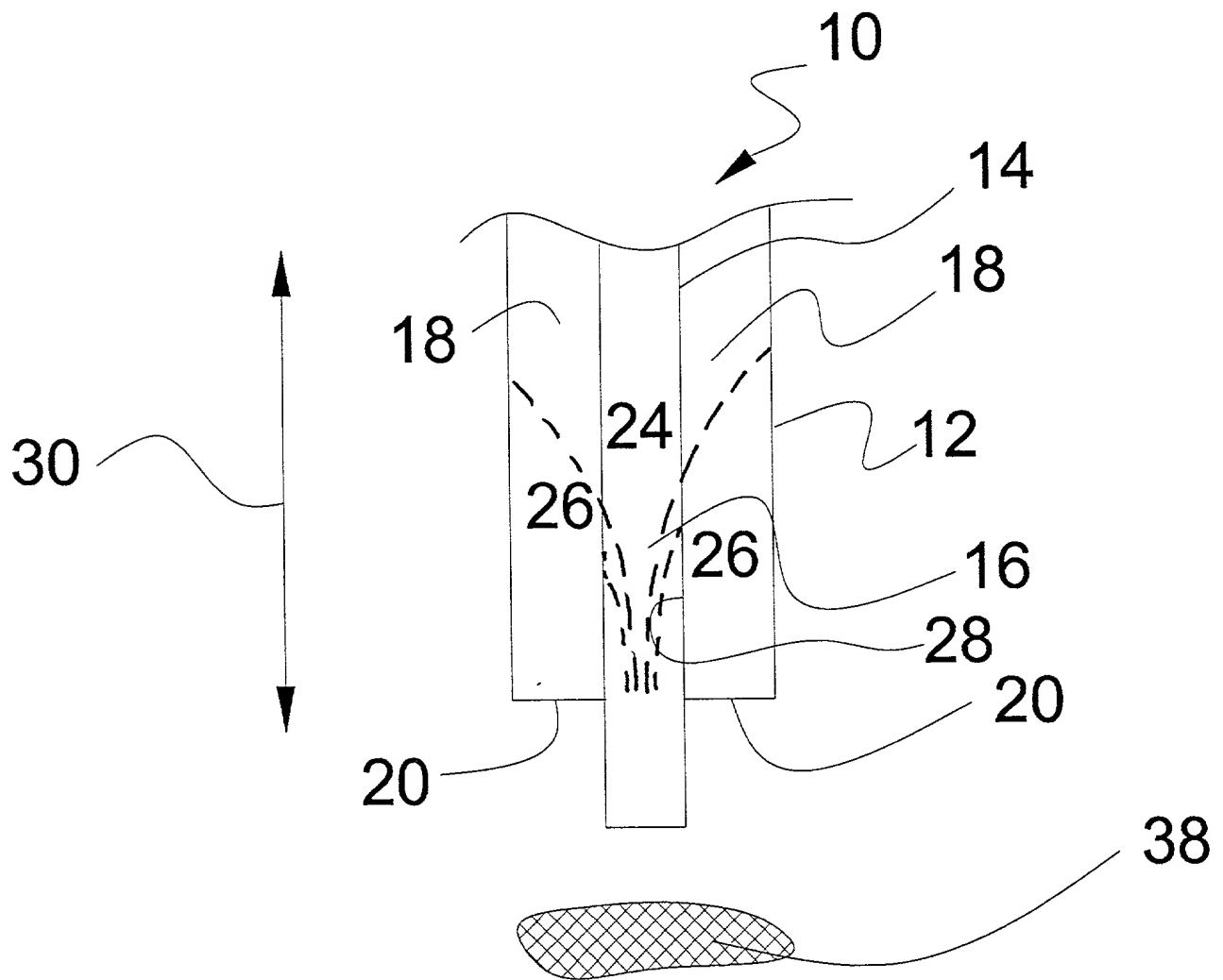


Figure 8

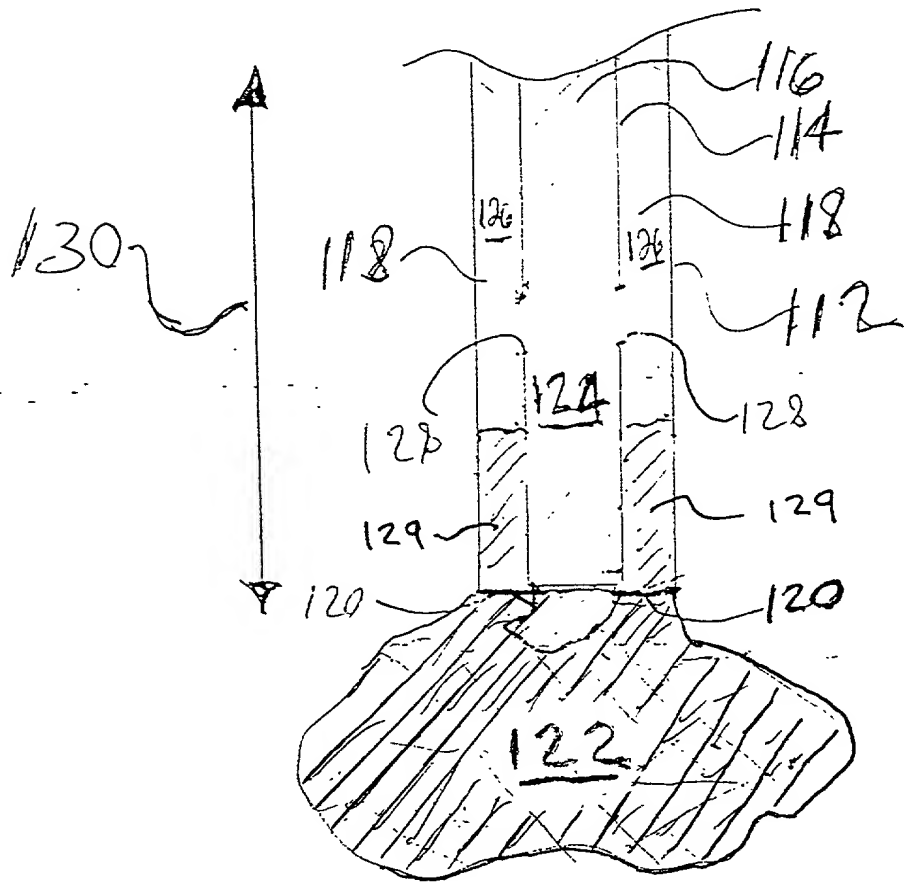
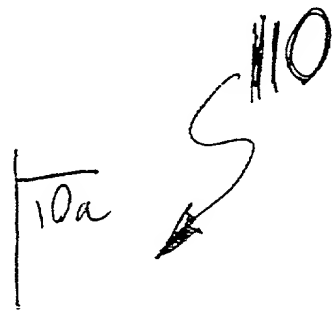


Figure 10

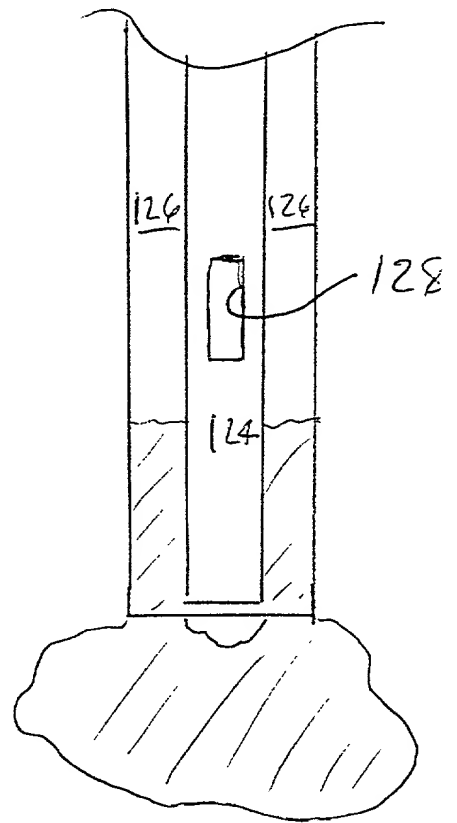


Figure 10a

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BOOK REVIEW

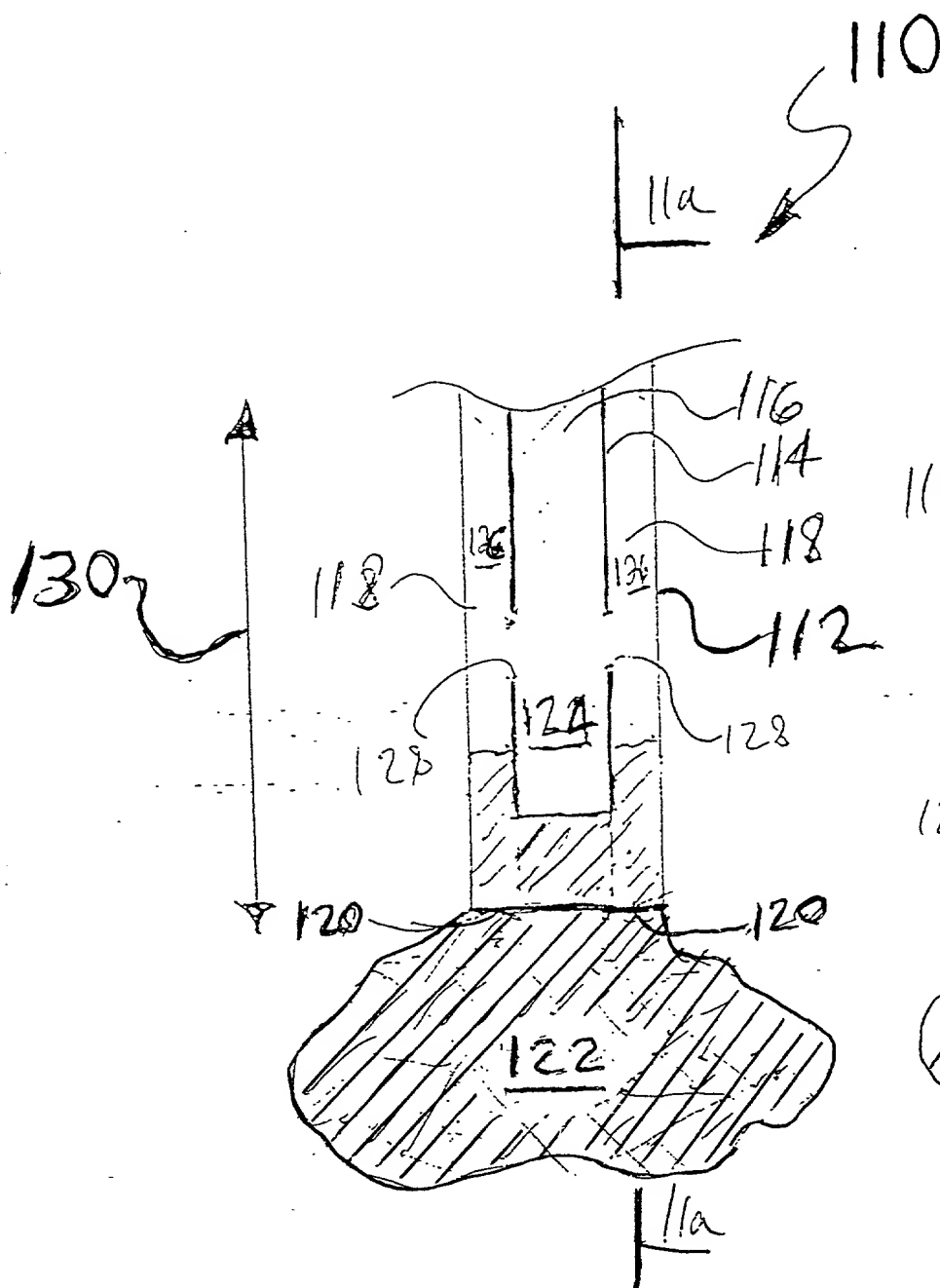


Figure 11

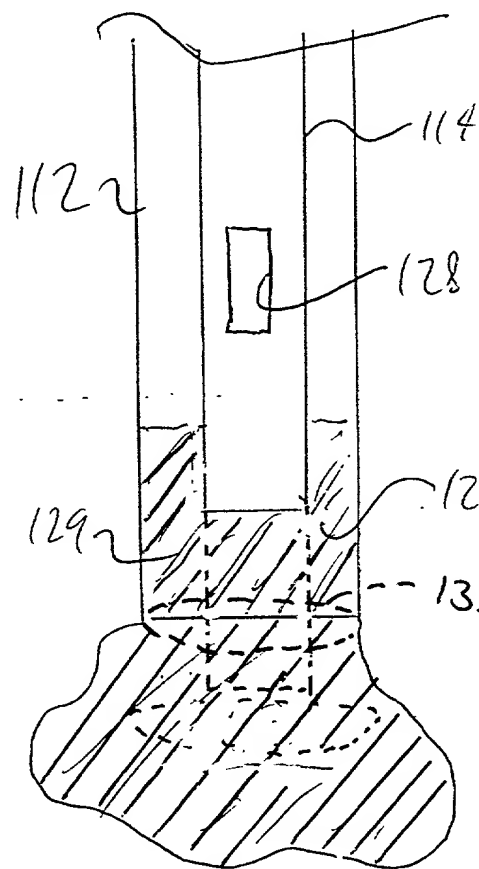


Figure 11a

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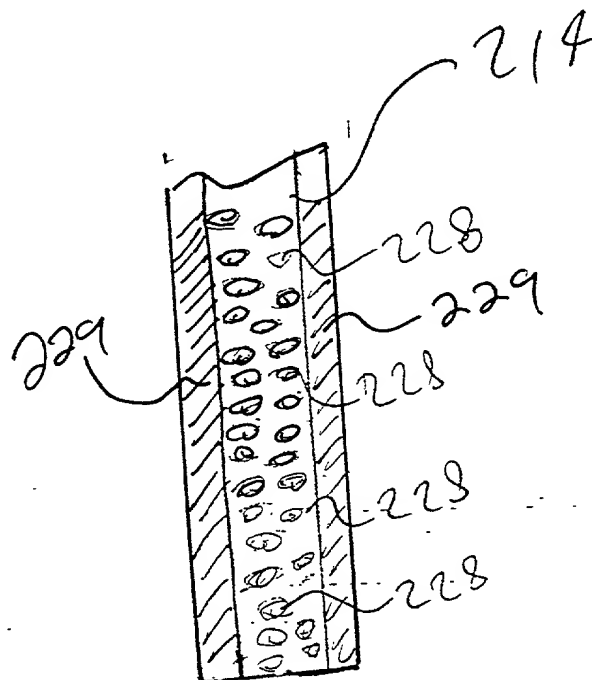


Figure 12

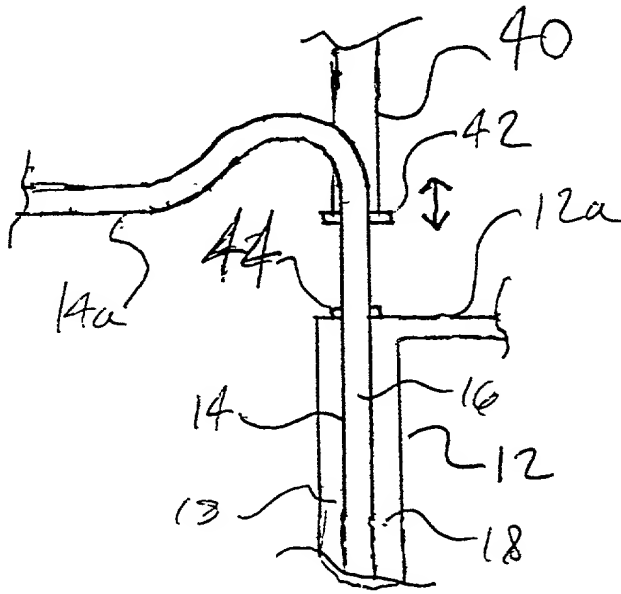
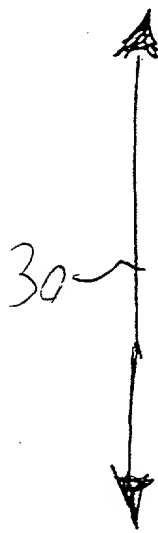


Figure 13

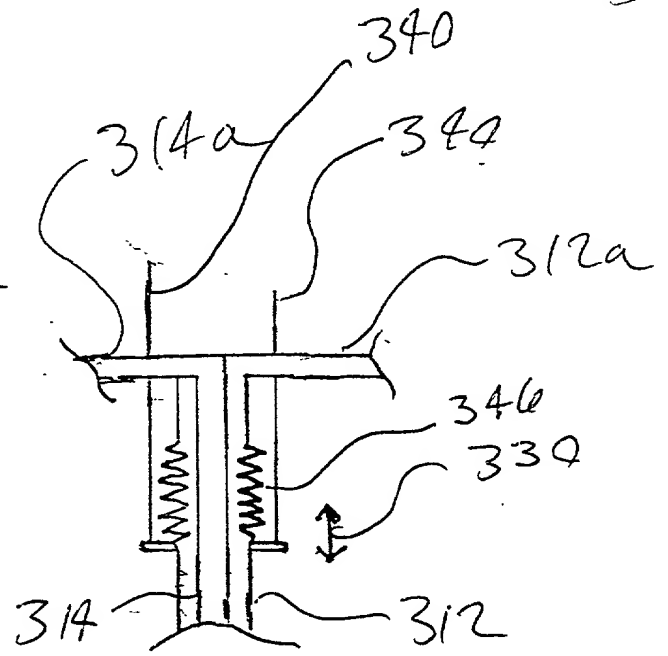


Figure 14

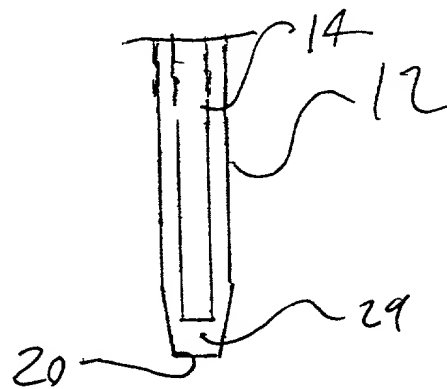


Figure 15

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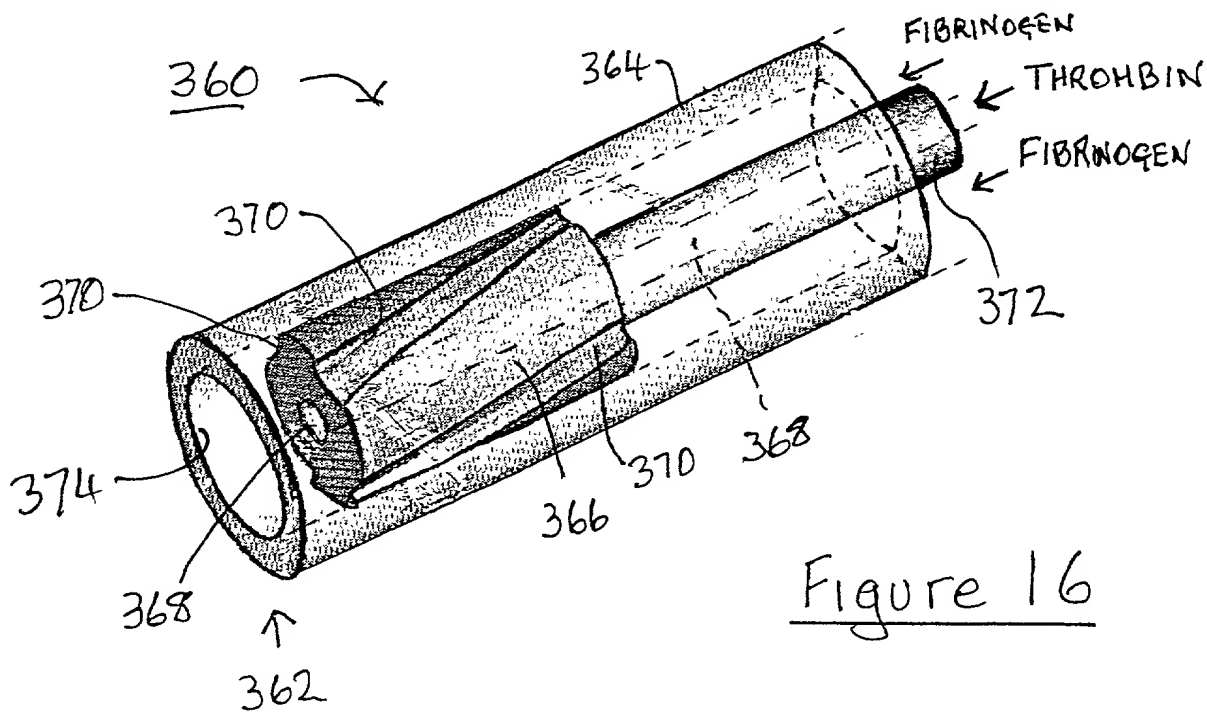


Figure 16

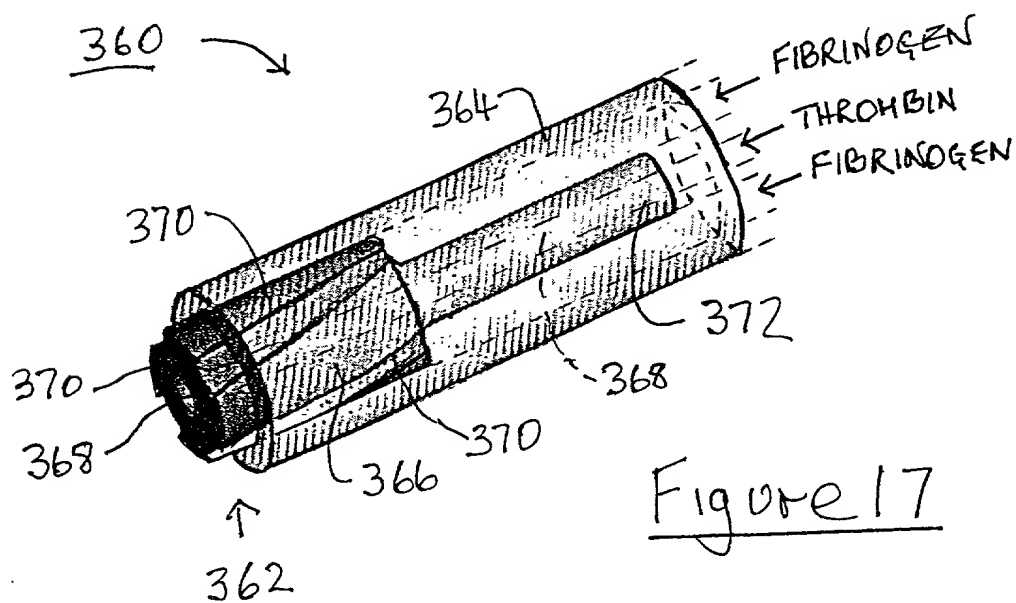


Figure 17

DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled: "COMPONENT MIXING CATHETER", the specification of which

☒ is attached hereto

☐ was filed _____ as United States Application Number _____

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR §1.56.

I hereby claim foreign priority benefits under 35 U.S.C. §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(e) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)	Country	Filing Date (mm/dd/yyyy)	Priority Claimed	Certified Copy Attached

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (mm/dd/yyyy)
60/102,636	October 1, 1998

I hereby claim the benefit under 35 U.S.C. §120 of any United States application(s) designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose information which is material to patentability

60/102,636

as defined in 37 CFR §1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

U.S. Parent Application Number	PCT Parent Number	Parent Filing Date (mm/dd/yyyy)	Parent Patent Number (if applicable)

As a named inventor, I hereby appoint Anthony H. Handal, Reg. No. 26,275 and as my attorney to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

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Handal & Morofsky
80 Washington Street
Norwalk, Connecticut 06854
Facsimile (203) 838-8794

I hereby declare that all statements made herein of my/our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful fals [X]
Additional inventors are being named on the separate sheet attached hereto.
We statements may jeopardize the validity of the application or any patent issued thereon.

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Inventor's Signature:	Date:

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